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Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir:

I would like to comment on the Revised Precautionary Measures to Redue the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood Products.

As indicated in the above document, previous and current studies fail to show the transmission of CJD by blood and blood products. Transmission of spongiform encephalopathy has only been achieved in animal models when contaminated cellular blood products were injected directly in the brain of hamsters. Studies have followed high risk populations such as hemophiliacs and thalassemics who died of neurological diseases without any evidence of TSE. Therefore, there appears to be very little chance of transmission of TSE through blood products.

1) Under introduction, it is stated that "there are public health reasons for immediate implementation of the recommendations regarding additional safeguards with respect to the new variant CJD".

Comment:

The "public health reasons" which are the basis for these recommendations should be made very clear. There is currently no evidence in the medical literature to support public health concerns over transfusion transmitted CJD or nvCJD.

2) Under Section III. A3, " The FDA believes that donors who have resided in the United Kingdom... may be at risk for exposure to nvCJD. As a precaution, FDA recommends that donors who have spent six months or more cumulatively in the United Kingdom from 1980 through 1996 ... be deferred indefinitely.

Comment:

It is unclear from reading the recommendation what the scientific / statistical basis for deciding on this length of time is. Statistical studies are needed to justify the benefits of deferring donors who have lived in the listed countries for a total of six months cumulative. To my knowledge, there are no such studies. Carrying this reasoning one step further, what then is the rationale for not deferring donors who have lived cumulatively one month? The 41 cases of nvCJD were born in England and lived there for 10 years between 1980 and 1996. The recommendation should be changed to reflect that important fact. Maybe deferring only donors born in England and having lived there for more than 10 years cumulatively between 1980 and 1986 would be a more reasonable approach.

3) Under Section IV-B, " The FDA recommends consignee notification for all plasma intended for further manufacture into derivatives. Consignee notification is recommended in order to effect withdrawal of plasma that has not already been pooled for manufacture. Later in that same paragraph, it is stated

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that the units of plasma that have already been pooled prior to consignee notification should not be pooled.

Comment:

This approach is inconsistent and does not appear to be rational. Either both should pulled or none should be pulled. These units should not be handled any differently from units for HIV, HTLV or hepatitis recalls.

4) Under section VI B, it is stated that: "No transmission of CJD or nvCJD by human blood components or plasma derivatives has been documented to date. Under subsection –1 it is recommended that the Circular of Information be revised to include under "side effects and Hazards " the following statement: "Because this product made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses and theoretically, the CJD agent." Similar modifications are recommended for Plasma derived products other than albumin and for plasma derived albumin.

Comment:

Since there have been no cases of CJD / nvCJD transmitted by blood or blood components why alert the public to this specific entity which is currently a theoretical risk. Why not then alert the public to the more real risk of potential hemolysis in a unit of blood which may be caused by extreme thermal variation or mechanical trauma? Why not mention the even more alarming risk of bacterial contamination, which is a real concern, especially in platelet products as evidenced by the recent FDA-sponsored seminar.

Blood centers in the United States are having the increasingly difficult task of providing more and more blood from an ever-decreasing number of donors. FDA regulations / recommendations have in the most part been successful in decreasing the risks of transfusion transmitted viral diseases. These regulations were based in sound scientific facts as proven by controlled studies. The above recommendations are based on theoretical risks and if implemented will have a devastating effect in the collection of blood.

The Wright Brothers would never have flown at Kitty Hawk and NASA would have never sent a man into space if they were to consider every possible theoretical risk. In striving to obtain the safest blood supply, let us keep things in perspective and address real risks first before we start looking at theoretical risks.

I look forward to seeing a Revised Version of this "Guidance for the Industry" addressing some of the above comments.

Thank you for the opportunity of commenting on this document.

Sincerely

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